ENCOMPASS

K120184

MAY - 2 2012

SECTION 5

510(k) Summary

Date Prepared: 21st Mar 2012

POWDER FREE NITRILE EXAMINATION GLOVE

5.1 Submitter's Name: Encompass Medical Supplies Inc Limited

5.2 Submitter's Address: Hua Shen Road, Wai Gao Qiao Free Trade Zone, Shanghai 200131.

5.3 Contact No: Tel: 0086-21-58666680 Fax: 0086-21-58666690

5.4 Contact Person: Mr. CJ Ang
Tel: +60-19-5125422

5.5 Name of Device: Powder Free Nitrile Examination Glove, Non Sterile (Blue Colored, Black Colored and White Colored)

Proprietary/Trade Name: I) Powder Free Nitrile Examination Glove
II) Other clients trade name and private labeling

Common Name: Nitrile Examination Glove
Classification Name: Patient Examination Glove (21 CER 880.6250)
Device Classification: Class I
Product Code: LZA

5.6 Predicate device: Powder Free Nitrile Examination Gloves, White Colored (K103734)

5.7 Identification of The Legally Marketed Device:
The Powder Free Colored Nitrile Examination Glove Class I patient examination gloves, Nitrile-80 LZA, meets all of the requirements of ASTM D6319-10 Standard Specification for Nitrile Examination Gloves for Medical Application.

5.8 Description of Device:
The Powder Free Nitrile Examination Glove Class I patient examination gloves, Nitrile-80 LZA, will meet all the current specification for ASTM D6319-10.

P. 1 of 2

5.9 Intended Use of the Device:

The Powder Free Nitrile Examination Gloves, Non Sterile (Blue Colored, Black Colored and White Colored) is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

5.10 Summary of The Technological Characteristics of The Device:

The technological characteristics of Powder Free Nitrile Examination Glove (Blue Colored, Blacked Colored and White Colored) are summarized below as compared to ASTM requirements and to the predicate devices (K103734):

Characteristic	Device Performance	Predicate Devices
Dimensions	Meets ASTM D6319-10	Meets ASTM D6319-00a
Physical Properties	Meets ASTM D0412-98	Meets ASTM D0412-98
Freedom From pin-holes	Meets ASTM D5151-06	Meets ASTM D5151-06
Powder Free Residue	Meets ASTM D6124-06	Meets ASTM D6124-06
Biocompatibility		
Dermal Sensitization	Passed – Not a Dermal Sensitization (ASTM F720-81 (Reapproved 2007))	Passed – Not a Dermal Sensitization (ASTM F720-81 (Reapproved 2007))
Primary Skin Irritation	Passed – Not a Skin Irritant (Consumer product safety Commission, Title 16, Chapter II, Part 1500)	Passed – Not a Skin Irritant (Consumer product safety Commission, Title 16, Chapter II, Part 1500)

5.11 Substantial Equivalent Based on Assessment of Non-Clinical Performance Data

Testing performed per ASTM D6319-10 Standard Specification for Nitrile Examination Cloves for Medical Application and 21 CFR 800.20. Gloves meet all the current ASTM D 6319-10.

Primary skin irritation testing in the rabbit and delayed dermal contact sensitization study in the guinea pigs indicate no irritation or sensitization.

There are no special labeling claims and we do not claim our gloves to be hypoallergenic.

5.12 Clinical Data: No clinical data was required.

5.13 Conclusion:

It can be concluded that the Powder Free Nitrite Examination Glove, Non Sterile (Blue Colored, Blacked Colored and White Colored) meet the ASTM standard or equivalent standard and FDA requirements.

Conclusively, we therefore claim that this device is substantially equivalent to its predicate device.

P. 2 of 2

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. CJ Ang
Encompass Medical Supplies Inc Limited
Hua Shen Road Wai Gao
Qiao Free Zone
Shanghai, China 200131

MAY - 2 2012

Re: K120184
Trade/Device Name: Powder Free Nitrile Examination Gloves, Non Sterile (Blue Colored, Black Colored and White Colored)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: April 13, 2012
Received: April 19, 2012

Dear Mr. Ang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ENCOMP

SECTION 3
INDICATION FOR USE STATEMENT

3.1 INDICATIONS FOR USE

510(k) Number (if known): K120184

Device Name: **Powder Free Nitrile Examination Gloves, Non Sterile (Blue Colored, Black Colored and White Colored).**

Indications For Use:

The Powder Free Nitrile Examination Gloves, Non Sterile (Blue Colored, Black Colored and White Colored) is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie-Wells

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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